

REMARKS

In the Final Office Action dated October 7, 2005, the Examiner maintained the rejections of claims 1-30, 33 and 34. Applicants have cancelled claims 25-30 and amended claim 33 herein. Accordingly, claims 1-24, 33 and 34 are pending.

In light of the amendments and the following remarks, Applicants respectfully request reconsideration and allowance of claims 1-24, 33 and 34.

Rejections under 35 U.S.C. § 103

The Examiner rejected claims 1-19 and 21-30 under 35 U.S.C. § 103(a) as being unpatentable over Gaynor *et al.* (U.S. 5,904,924) ("Gaynor"), and claims 1-34 under 35 U.S.C. §103(a) as being unpatentable over Perkes (WO 99/07400) ("Perkes"). In particular, the Examiner alleged that Applicants had not shown unexpected results that arise from the particular selection of the Muscat grape. For example, the Examiner stated that "the cited figure of 60% inhibition of platelet aggregation used by the applicant to distinguish above the prior art does not list any sort of standard deviation. Without such a standard deviation, the statistical significance of such a figure is difficult to ascertain." In a previous Office Action dated February 3, 2003, the Examiner stated that "applicant has not provided comparisons related to the results obtained by using that particularly claimed variety of grape seed [Muscat] extract. . . It is suggested that applicant demonstrate, via a side-by-side comparison, the results obtained when using the grape seed extract of the cited reference and those results obtained by utilizing the claimed Muscat grape seed extract."

Applicants respectfully disagree for the reasons of record set forth in prior responses and as stated below. Nevertheless, in order to further prosecution, Applicants have performed side-by-side comparisons as suggested by the Examiner in order to further establish the nonobviousness of the recited claims, as discussed more fully below.

Claim 1 recites a dietary supplement comprising a grape skin extract and a Muscat variety grape seed extract. The only composition disclosed in the Gaynor reference is a 969 gram mixture containing 300 mg of grape skin extract and 40 mg of grape seed extract, representing a 7.5 to 1 ratio of grape skin extract to grape seed extract. The Examiner has acknowledged that Gaynor does not teach the claimed range of ratios of grape skin extract to

grape seed extract. Moreover, at no point does the Gaynor reference suggest the combination of a grape skin extract and a Muscat variety grape seed extract. In fact, the Gaynor reference never mentions combining a Muscat variety grape seed extract with a grape skin extract to form the presently claimed composition.

The Perkes reference is similarly deficient. The Perkes reference discloses three formulations containing grape skin extracts and grape seed extracts. The Perkes reference, however, does not teach or suggest any composition containing a grape skin extract in combination with a Muscat variety grape seed extract, as present claims 1-24 require. Further, at no point does the Perkes reference teach or suggest making a supplement having the claimed range of ratios of grape skin extract to grape seed extract. In fact, a person having ordinary skill in the art reading the Perkes reference would not have been motivated to make a supplement having a grape skin extract to grape seed extract ratio between 3 to 1 and 5 to 1, given that the three specific formulations exemplified in the Perkes reference have ratios (1.66 to 1, see page 17; 1.2 to 1, see page 19; and 20.5 to 1, see page 21) well outside the range of ratios presently recited in the claims. Thus, both the Gaynor and Perkes references fail to suggest that a person having ordinary skill in the art should make the presently claimed compositions.

As additional evidence of nonobviousness, Applicants note that compositions containing a Muscat grape seed extract exhibit surprisingly high reductions in platelet aggregation activity when evaluated in a side-to-side experiment to compositions containing other varieties of grape seed extracts. As shown in the attached Declaration signed by Erin Stone, an employee of the Assignee of the present application, compositions containing a Muscat grape seed extract demonstrated statistically significant increases in platelet aggregation inhibition activity in two different supplement formulations ($83.47\% \pm 2.1\%$ and $77.8\% \pm 0\%$, respectively) as compared to identical compositions containing one or the other of two grape seed extracts, grape seed extract 1 and grape seed extract 2, ($4.55\% \pm 14.32\%$ and $-9.9\% \pm 10\%$ for grape seed extract 1; $46.17\% \pm 17.98\%$ and $46.7\% \pm 22.3\%$ for grape seed extract 2). As the Examiner will note, the Declaration sets forth standard deviations as well as p values, thus allowing the Examiner to evaluate the statistical significance of the results. Because formulations including Muscat grape seed extract exhibit such surprising results relative to other grape seed extracts, Applicants respectfully assert that the claims are not obvious.

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In light of the above, Applicants respectfully request the withdrawal of the rejections of claims 1-24, 33 and 34 under 35 U.S.C. § 103(a).

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CONCLUSION

Applicants respectfully assert that all claims are in condition for allowance, which action is requested. The Examiner is invited to telephone the under-signed if such would expedite prosecution.

Enclosed is a \$790 check for the Request for Continued Examination fee and a \$1,020 check for the Petition for Extension of Time fee (3 months). Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 4/7/06

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